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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,769	07/10/2003	Yu Momose	2630 US1P	3491

23115 7590 09/26/2006

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
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SUITE 500
LINCOLNSHIRE, IL 60069

EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,769

Applicant(s)

MOMOSE ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6,8-13,15,18,20-24,29,30,32-38,43 and 45,47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1,3,6,8-13,15,18,20-24,29,30,32-38,43,45,47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 3, 6, 8-12, 15, 29, 30, 32-38, 43, 45-47 are drawn to a method of preventing or treating diseases comprising administering a compound of the formula in claim 1, wherein X is oxygen, classified in class 514, subclass 374.
 - II. Claims 1, 3, 6, 8-11, 13, 18, 20-24 drawn to a method of preventing or treating diseases comprising administering a compound of the formula in claim 1, wherein X is sulfur, classified in class 514, subclass 365.
 - III. Claims 1, 3, 6, 8-11 drawn to a method of preventing or treating diseases comprising administering a compound of the formula in claim 1, wherein X is nitrogen, classified in class 514, subclass 385.
1. Inventions groups I-III are unrelated each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation. Particularly, the different inventions herein represent separate and distinct methods. They differ with respect to ingredients, method steps and final results. They therefore have different issues regarding patentability and enablement and represent patentable distinct subject matter. It is noted that a reference that make one invention obvious would not necessarily make the others obvious, and practice one of the invention would not infringe the others as they employ structurally distinct compounds.

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Each of the above groups are further restricted as follow:

- A) method for preventing or treating chronic pain;
- B) method of preventing or treating amyotrophic lateral sclerosis;
- C) method for preventing or treating diabetic cardiopathy;
- D) method for preventing or treating peripheral nerve injury;
- E) method for preventing or treating spinal injury;
- F) method for preventing or treating multiple sclerosis;
- G) method for preventing or treating cerebral ischemic disease,
- H) method for preventing or treating senile dementia of Alzheimer type;
- I) method for preventing or treating Parkinson's disease;
- K) method for preventing or treating Huntington's chorea;
- L) method for preventing or treating depression;
- M) method for preventing or treating inflammatory bowel disease;
- N) method for preventing or treating behavioral abnormalities accompanied by dementia
- O) method for preventing or treating anxiety.

2. The inventions of Group A-O represent separate and distinct methods. They differ with respect to ingredients, method steps and final results. They therefore have different issues regarding patentability and enablement and represent patentable distinct subject matter.

Particularly, the several inventions above are independent and distinct, each from the other, as they are directed to treating diseases with distinct etiologies and symptoms, and have acquired a separate status in the art of treating as a separate subject matter for inventive effect and require independent searches. It is noted that a reference to one treatment would not be a reference to

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another treatment under 35 U.S.C. 103. Further, the claims read on a multitude of compounds, and a variety of disorders, which would require many field of searches that would be an undue burden on the Examiner. Therefore, restriction for examination purposes is proper.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Claims 1, 3, 6, 8-12, 15, 18, 20-24, 29, 30, 32-38, 43, 45-47 are generic to the following disclosed patentably distinct species: various compounds encompassed thereby. The species are independent or distinct because of the structural distinct feature. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

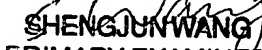
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SHENGJUNWANG
PRIMARY EXAMINER
Shengjun Wang
Primary Examiner
Art Unit 1617